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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/948,124 10/09/97 REINHERZ

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HM22/0620  
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EXAMINER

BANSAL, G

ART UNIT

PAPER NUMBER

1642

20

DATE MAILED:

06/20/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

0894824

Applicant(s)

Reinherz et al

Examiner

ef/bsaal

Group Art Unit

1642

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE -3- MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 3/20/00
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 41, 45, 53-63 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 41, 45, 53-63 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_.

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☒ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

Office Action Summary

Art Unit: 1642

**DETAILED ACTION**

**DETAILED ACTION**

1. Applicant's amendment filed March 2, 2000 (Paper No: 16/C) is acknowledged. Accordingly, claims 41 and 45 have been amended. Claims 1-40, 42, 44, 46-52 have been cancelled. Claims 53-63 have been added. Claims 41, 45, and 53-63 are being examined.

***Response to Arguments***

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3A. Rejection of claims 41-45 under 35 U.S.C. 112, 2nd paragraph are withdrawn in view of the arguments and amendments presented by Applicant.

3B. Rejection of claims 41, 45 and new claims 53-63 under 35 U.S.C. 103 are maintained as set forth in the previous office action. Applicant's arguments have been considered but are not persuasive. Applicant argues that Fearnhead does not teach a method of identifying agents that enhance caspase activity. Applicant states that they took Examiner's suggestion to incorporate the term "isolated" and indicate that as per Examiner's suggestion the "isolated caspase" should render it unobvious. Examiner has clearly only suggested the use of the term **may** render it unobvious. It appears that Applicant discloses that a novel caspase was identified in the thymocytes by Applicant and therefore Examiner suggested that inclusion of an isolated thymocyte specific caspase may obviate the prior art rejection. However, upon further consideration in light of the amendments and arguments, it appears that the Fearnhead et al reference is still applicable as prior art. Fearnhead et al teach that caspases are involved in apoptosis in thymocytes. Fearnhead et al also teach an assay method whereby this caspase activity in thymocytes was assayed by a method wherein thymocytes were incubated with dexamethasone, thapsigargin, etoposide which are all activators of apoptosis, and wherein

Art Unit: 1642

apoptosis was assessed by monitoring cell death. Simultaneously PARP hydrolysis, which was an indication of caspase activity was assessed. The conclusion that apoptosis was mediated by caspases in thymocytes was reached by Fearnhead et al by including inhibitors of caspases and assessing an inhibition of apoptosis in these cells. Thus, Fearnhead intrinsically teaches that agents such as dexamethasone, thapsigargin and others as mentioned can increase the activity of thymocyte caspases. In fact Fearnhead also indicates (page 287, column 1, last paragraph) that TLCK was an agent that could function as an enhancer of apoptosis induced by most stimuli. Therefore, Fearnhead's teachings makes it obvious for one of ordinary skill in the art to practice the claimed invention.

*New Ground of rejection*

*Claim Rejections - 35 U.S.C. § 112*

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 41, 45, 53-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 41 and 45 are ambiguous in that it is not clear how a method of identifying an agent that enhances the activity of an isolated caspase (which suggests that the intrinsic catalytic activity of the enzyme is increased) is applicable to situations wherein the amounts of the caspases are increased (which would be an obvious result in that when the amount of an enzyme is increased the activity is automatically increased) as specified in the dependent claims 53-63.

B. Claim 56 and 61 are indefinite in that it is not clear what is encompassed by "prolonged" and in comparison to what? Prolonged refers to duration of time whereas enhancement refers to an increase in activity? Clarification is requested.

Art Unit: 1642

C. Claims 57 and 62 are indefinite in that it is not clear how they each further limit the scope of their respective parent claims.

6. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242 or (703) 305-3014.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Geetha P. Bansal whose telephone number is (703) 305-3955. The examiner can normally be reached on Mondays to Thursdays from 7:00am to 4:30pm and alternate Fridays from 7:00am to 3:30pm. A message may be left on the examiner's voice mail service.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Anthony Caputa, can be reached on (703) 308- 4995.

8. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

June 2, 2000

*Geetha P. Bansal*  
GEETHA P. BANSAL  
PATENT EXAMINER